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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
07/158,652	02/22/1988	MARC ALIZON	PAST-010-A	3369

7590 05/02/2003

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	07/158,652	ALIZON ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Jeffrey Fredman	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 March 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 133-141 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 133-141 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ .
- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_ .
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_ .

## DETAILED ACTION

### ***Status***

1. Claims 1-132 were cancelled
2. Claims 133-141 are pending.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 133-141 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number'' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

Claims 131-141 is drawn to any complete HIV LTR, with or without appended sequence. This claim encompasses an enormous genus of nucleic acids which are

different from the single HIV LTR sequence that is disclosed in the specification. The genus includes variants for which no written description is provided in the specification. Thus, applicant has express possession of only one particular HIV LTR sequence in a genus which comprises hundreds of millions of different possibilities. Here, no common element or attributes of the sequences are disclosed, not even the presence of certain domains. No structural limitations or requirements which provide guidance on the identification of sequences which are necessary to function as an HIV LTR are provided.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

"A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outline[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material."

In the current situation, the definition of the HIV LTR in claims 133-141 lacks any specific structure. This is precisely the situation of naming a type of material which is

generally known to likely exist, but except for the one sequence disclosed, fails to provide descriptive support for the generic claim to any complete HIV LTR.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound solely but its functional utility, as an HIV LTR, without any definition of the particular sequences claimed.

In the instant application, certain specific SEQ ID NOs are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise complete HIV LTR sequences. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 133-141 are rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al (U.S. Patent 6,001,977).

Chang teaches nucleic acid probes of HIV-1 sequence selected from the HIV sequence (column 9, lines 25-62 and column 10, line 65 to column 11, line 32), where the specific sequence is disclosed as SEQ ID NO: 4, for example (columns 19-28).

The alignment of the Query HIV sequences of Chang and the subject sequences of the present application in the region between nucleotides 5670 and 8132 are presented below.

Query:	aaagagcaga 5569
Sbjct:	aaagagcaga 5755
env	1 K E Q

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Query: 5570 agacagtggcaatgagagtgaaggagaaatcagcacttgtggagatgggggtggagat 5629  
||||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 5756 agacagtggcaatgagagtgaaggagaaatcagcacttgtggagatgggggtggaaat 5815  
env 4 K T V A M R V K E K Y Q H L W R W G W K

Query: 5630 ggggcaccatgctccttggatgtttagatctgttagtgcatacagaaaaattgtgggtca 5689  
||||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 5816 ggggcaccatgctccttggatattgttagatctgttagtgcatacagaaaaattgtgggtca 5875  
env 24 W G T M L L G I L M I C S A T E K L W V

Query: 5690 cagtctattatgggtacctgtgtggaaagcaaccaccactctatTTTgtgcatacg 5749  
||||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 5876 cagtctattatgggtacctgtgtggaaagcaaccaccactctatTTTgtgcatacg 5935  
env 44 T V Y Y G V P V W K E A T T T L F C A S

Query: 5750 atgctaaagcatatgatacagaggtacataatgtttggccacacatgcctgtgtaccca 5809  
||||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 5936 atgctaaagcatatgatacagaggtacataatgtttggccacacatgcctgtgtaccca 5995  
env 64 D A K A Y D T E V H N V W A T H A C V P

Query: 5810 cagaccccaaccccacaagaagtagtattggtaatgtgacagaaaaatttaacatgtgga 5869  
||||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 5996 cagaccccaaccccacaagaagtagtattggtaatgtgacagaaaaatttaacatgtgga 6055  
env 84 T D P N P Q E V V L V N V T E N F N M W

Query: 5870 aaaatgacatggtagaacagatgcatacgaggatataatcagttatggatcaaagcctaa 5929  
||||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 6056 aaaatgacatggtagaacagatgcatacgaggatataatcagttatggatcaaagcctaa 6115  
env 104 K N D M V E Q M H E D I I S L W D Q S L

Query: 5930 agccatgtgtaaaattaaccccactctgtgttagttaaagtgcactgattgaagaatg 5989  
||||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 6116 agccatgtgtaaaattaaccccactctgtgttagttaaagtgcactgattgggatg 6175  
env 124 K P C V K L T P L C V S L K C T D L G N

Query: 5994 taataccaatagtagtagcgggagaatgataatggagaaggagagataaaaaactgctc 6053  
||||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 6195 taataccaatagtagtagcgggagaatgatggagaaggagagataaaaaactgctc 6254  
env 151 N T N S S S G E M M M E K G E I K N C S

Query: 6054 tttcaatatcagcacaagcataagaggtaaaggtaaggcagaaagaatatgcannnnnnataa 6113  
||||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 6255 tttcaatatcagcacaagcataagaggtaaaggtaaggcagaaagaatatgcatttttataa 6314  
env 171 F N I S T S I R G K V Q K E Y A F F Y K

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Query: 6114 acttgatataataccaatagataatgatactaccagctatacgttacaagttgtacac 6173  
Sbjct: 6315 acttgatataataccaatagataatgatactaccagctatacgttacaagttgtacac 6374  
env 191 L D I I P I D N D T T S Y T L T S C N T

Query: 6174 ctcagtcatcacacaggcgtccaaaggtagtacatttgcggcaattccatacattattg 6233  
Sbjct: 6375 ctcagtcatcacacaggcgtccaaaggtagtacatttgcggcaattccatacattattg 6434  
env 211 S V I T Q A C P K V S F E P I P I H Y C

Query: 6234 tgccccggctggtttgcgattctaaaatgtataataaagacgttcaatggAACAGGACC 6293  
Sbjct: 6435 tgccccggctggtttgcgattctaaaatgtataataaagacgttcaatggAACAGGACC 6494  
env 231 A P A G F A I L K C N N K T F N G T G P

Query: 6294 atgtacaaatgtcagcacagtacaatgtacacatggAAATTAGGCCAGTAGTATCAACTCA 6353  
Sbjct: 6495 atgtacaaatgtcagcacagtacaatgtacacatggAAATTAGGCCAGTAGTATCAACTCA 6554  
env 251 C T N V S T V Q C T H G I R P V V S T Q

Query: 6354 actgctgttaatggcagtctggcagaagaAGAGGGTAGTAATTAGATCTGCCAATTCAC 6413  
Sbjct: 6555 actgctgtgaatggcagtctgcagaagaAGAGGGTAGTAATTAGATCTGCCAATTCAC 6614  
env 271 L L L N G S L A E E E V V I R S A N F T

Query: 6414 agacaatgctaaaaccataatagtagtacagctgaaccaatctgttagAAATTGTACAAG 6473  
Sbjct: 6615 agacaatgctaaaaccataatagtagtacagctgaaccaatctgttagAAATTGTACAAG 6674  
env 291 D N A K T I I V Q L N Q S V E I N C T R

Query: 6474 acccaacaacaatacagaAAAAGTATCCGTATCCAGAGAGGACCGAGGGAGAGCATTGT 6533  
Sbjct: 6675 acccaacaacaatacagaAAAAGTATCCGTATCCAGAGAGGACCGAGGGAGAGCATTGT 6734  
env 311 P N N N T R K S I R I Q R G P G R A F V

Query: 6534 tacaataggAAAATAGGAATATGAGACAAGCACATTGTAACATTAGTAGAGCAAAATG 6593  
Sbjct: 6735 tacaataggAAAATAGGAATATGAGACAAGCACATTGTAACATTAGTAGAGCAAAATG 6794  
env 331 T I G K I G N M R Q A H C N I S R A K W

Query: 6594 gaataacacttAAAACAGATAGATAAGAGACAACATTGGAATAATAAAAC 6653  
Sbjct: 6795 gaatGCCACTTAAAACAGATAGCTAGCAAATTGGAATAATAAAAC 6854  
env 351 N A T L K Q I A S K L R E Q F G N N K T

Query: 6654 aataatcttaagcagtccctcaggagggaccagaaattgtaacgcacagtttaattg 6713  
|||||||  
Sbjct: 6855 aataatcttaagcaatccctcaggagggaccagaaattgtaacgcacagtttaattg 6914  
env 371 I I F K Q S S G G D P E I V T H S F N C

Query: 6714 tggagggaaattttctactgttaattcaacacaactgtttaatagtacttggttaatag 6773  
|||||||  
Sbjct: 6915 tggagggaaattttctactgttaattcaacacaactgtttaatagtacttggttaatag 6974  
env 391 G G E F F Y C N S T Q L F N S T W F N S

Query: 6774 tacttgaggactaaagggtcaaataacactgaaggaagtgacacaatcaccccccattg 6833  
|||||||  
Sbjct: 6975 tacttgaggactgaagggtcaaataacactgaaggaagtgacacaatcacactccatg 7034  
env 411 T W S T E G S N N T E G S D T I T L P C

Query: 6834 cagaataaaacaattataaacatgtggcaggaagttagaaaaagcaatgttatccccctcc 6893  
|||||||  
Sbjct: 7035 cagaataaaacaattataaacatgtggcaggaagttagaaaaagcaatgttatccccctcc 7094  
env 431 R I K Q F I N M W Q E V G K A M Y A P P

Query: 6894 catcagtggacaaatttagatgttcatcaaattacaggcgtctattaacaagagatgg 6953  
|||||||  
Sbjct: 7095 catcagcgacaaatttagatgttcatcaaattacaggcgtctattaacaagagatgg 7154  
env 451 I S G Q I R C S S N I T G L L T R D G

Query: 6954 tggtaatagcaacaatgagtcgcagatcttcagacacctggaggaggatatgagggacaa 7013  
|||||||  
Sbjct: 7155 tggtaataacaacaatgggtcccgagatcttcagacacctggaggaggatatgagggacaa 7214  
env 471 G N N N N G S E I F R P G G D M R D N

Query: 7014 ttggagaagtgaattataatataaagttagtaaaaattgtaccattaggatgcacc 7073  
|||||||  
Sbjct: 7215 ttggagaagtgaattataatataaagttagtaaaaattgtaccattaggatgcacc 7274  
env 491 W R S E L Y K Y K V V K I E P L G V A P

Query: 7074 caccaggcaaaagagaagagtggcagagagaaaaagagcgtggaaataggagctt 7133  
|||||||  
Sbjct: 7275 caccaggcaaaagagaagagtggcagagagaaaaagagcgtggaaataggagctt 7334  
env 511 T K A K R R V V Q R E K R A V G I G A L

Query: 7134 gttcctgggtcttggaggcagcaggaagcactatggcgcagcgtcaatgacgctgac 7193  
|||||||  
Sbjct: 7335 gttcctgggtcttggaggcagcaggaagcactatggcgcacggtcaatgacgctgac 7394  
env 531 F L G F L G A A G S T M G A R S M T L T

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Query: 7194 ggtacaggccagacaattattgtctggatatgtcagcagcagaacaattgctgagggc 7253  
|||||||  
Sbjct: 7395 ggtacaggccagacaattattgtctggatatgtcagcagcagaacaattgctgagggc 7454  
env 551 V Q A R Q L L S G I V Q Q Q N N L L R A

Query: 7254 tattgaggcgcaacagcatctgttgcactcacagtctgggcatcaagcagctccagggc 7313  
|||||||  
Sbjct: 7455 tattgaggcgcaacagcatctgttgcactcacagtctgggcatcaagcagctccagggc 7514  
env 571 I E A Q Q H L L Q L T V W G I K Q L Q A

Query: 7314 aagaatcctggctgtggaaagatacctaaggatcaacagctcctgggattttgggttg 7373  
|||||||  
Sbjct: 7515 aagaatcctggctgtggaaagatacctaaggatcaacagctcctgggnattttgggttg 7574  
env 591 R I L A V E R Y L K D Q Q L L G I W G C

Query: 7374 ctctggaaaactcattgcaccactgtgtgccttggaatgtctgtggagtaataaattc 7433  
|||||||  
Sbjct: 7575 ctctggaaaactcattgcaccactgtgtgccttggaatgtctgtggagtaataaattc 7634  
env 611 S G K L I C T T A V P W N A S W S N K S

Query: 7434 tctggAACAGATTGGAATAACATGACCTGGATGGAGTGGACAGAGAAATTACAATT 7493  
|||||||  
Sbjct: 7635 tctggAACAGATTGGAATAACATGACCTGGATGGAGTGGACAGAGAAATTACAATT 7694  
env 631 L E Q I W N N M T W M E W D R E I N N Y

Query: 7494 cacaagcttaatacactccttaattgaagaatcgcaaaaccagcaagAAAAGAATGAACA 7553  
|||||||  
Sbjct: 7695 cacaagcttaatacattccttaattgaagaatcgcaaaaccagcaagAAAAGAATGAACA 7754  
env 651 T S L I H S L I E E S Q N Q Q E K N E Q

Query: 7554 agaattattggatttagataatggcaagtttgttgcattttttacataacaattt 7613  
|||||||  
Sbjct: 7755 agaattattggatttagataatggcaagtttgttgcattttttacataacaattt 7814  
env 671 E L L E L D K W A S L W N W F N I T N W

Query: 7614 gctgtggtatataaaattattcataatgatagtaggaggcttggtaggtttaaatgt 7673  
|||||||  
Sbjct: 7815 gctgtggtatataaaatattcataatgatagtaggaggcttggtaggtttaaatgt 7874  
env 691 L W Y I K I F I M I V G G L V G L R I V

Query: 7674 ttttgctgtactttctgttagtgaatagatgttaggcaggatattcaccattatcgttca 7733  
|||||||  
Sbjct: 7875 ttttgctgtactttctatagtgaatagatgttaggcaggatattcaccattatcgttca 7934  
env 711 F A V L S I V N R V R Q G Y S P L S F Q

Query: 7734 gacccacctccaaatcccgaggggacccgacaggcccgaaggaatagaagaagggtgg 7793  
||||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 7935 gacccacctccaaaccccgaggggacccgacaggcccgaaggaatagaagaagggtgg 7994  
env 731 T H L P T P R G P D R P E G I E E E G G

Query: 7794 agagagagacagagacagatccattcgattagtgaacggatccttagcacttatctggaa 7853  
||||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 7995 agagagagacagagacagatccattcgattagtgaacggatccttagcacttatctggaa 8054  
env 751 E R D R D R S I R L V N G S L A L I W D

Query: 7854 cgatctgcggagcctgtgcctctttagtaccaccgcgtttagagacttactcttgattgt 7913  
||||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 8055 cgatctgcggagcctgtgcctctttagtaccaccgcgtttagagacttactcttgattgt 8114  
env 771 D L R S L C L F S Y H R L R D L L I V

Query: 7914 aacgaggattgtggaaacttctggacgcagggggtggaaagccctcaaataattgggtggaa 7973  
||||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 8115 aacgaggattgtggaaacttctggacgcagggggtggaaagccctcaaataattgggtggaa 8174  
env 791 T R I V E L L G R R G W E A L K Y W W N

Query: 7974 tctcctacagtattggagtcaaggagctaaa  
||||||| ||||| ||||| ||||| |||||

Sbjct: 8175 tctcctacagtattggagtcaaggagctaaa  
env 811 L L Q Y W S Q E L K

It is noted that with regard to, for example, the sequence region claimed, there are 25 nucleotide differences between the sequences. It is noted that the art recognizes that sequencing errors occur in a range between 0.3 % and 2.5%, as evidenced by Richterich (Genome Research (1998) 8:251-259). However, these error rates are determined using technology that was significantly more advanced than that in 1984, when sequencing error rates were likely significantly higher. In the 2,462 nucleotide sequence which is the first sequence of claim 30, 25 errors would represent approximately a 1% error rate. Thus, these sequences are identical within the error range available and the anticipation rejection is proper.

***Response to Arguments***

5. Applicant's arguments filed March 7, 2003 have been fully considered but they are not persuasive.

First, Applicant will note the written description rejection, which addresses the absence of sequence attached to the "HIV LTR" phrase.

Second, Applicant argues that the current claims are distinguished from the Chang prior art because Chang expressly recognizes that part of the LTR sequence is not completely disclosed and the claims encompass that region. In particular, Applicant relies upon the specification of Chang, which notes at page 9 that "Because there are two SstI recognition sites within the LTR of HTLV-III DNA, one LTR region is not present in the cloned DNA sequence removed from the Lambda10 vector. As a result, a small (approximately 200 bp) fragment of the HTLV-III DNA is missing."

There are two separate problems with this argument. First, applicant has not shown which specific sequence was absent in Chang. HIV has two LTR regions, a 5' LTR and a 3' LTR. A review of genbank record K03455 demonstrates that the 5' LTR has the two Sst I sites discussed by Chang while the 3' LTR does not, thus indicating that Chang teaches a complete 3' LTR. Thus, to the extent that the claim requires a complete HIV LTR, Chang teaches a complete 3' LTR. Second, with regard to the sequences disclosed, none of these overlap or comprise the missing region in the 5' LTR. The 5' LTR region is shown below, with the two SstI sites underlined and in bold.

1 tggaaggct aattcactcc caacgaagac aagatatcct tgatctgtgg atctaccaca

61 cacaaggcta ctccctgat tagcagaact acacaccagg gccagggatc agatatccac

121 tgaccttgg atggtgctac aagctagtac cagttgagcc agagaagtttta gaagaaggcca  
181 acaaaggaga gaacaccagc ttgttacacc ctgtgagcct gcatggaatg gatgaccgg  
241 agagagaagt gtttagagtgg aggttgaca gccgcctagc atttcatcac atggcccag  
301 agctgcatcc ggagtacttc aagaactgct gacatcgagc ttgctacaag ggactttccg  
361 ctggggactt tccagggagg cgtggcctgg gcgggactgg ggagtggcga gccctcagat  
421 cctgcatata agcagctgct tttgcctgt actgggtctc tctggttaga ccagatctga  
481 gcctgggagctctctggcta actaggaaac ccactgctta agcctaata aagctgcct  
541 tgagtgccttc aagttagtgtg tgcccgctg ttgtgtgact ctggtaacta gagatccctc  
601 agacccttt agtcagtgtg gaaaatctct agcagtggcg cccgaacagg gaccgtaaaag  
661 cgaaaggaa accagagggagctc

So it is this region between nucleotides 486 and 682 which is missing in Chang, according to Chang. None of applicant's claims are drawn to this region in any specific way, and since Chang teaches a complete 3' HIV LTR, Chang continues to meet the limitations of the claim.

#### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

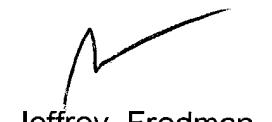
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman  
Primary Examiner  
Art Unit 1634

April 30, 2003